510(k) Summary
for the
E.M.S. ELECTRO MEDICAL SYSTEMS SA
EMS Piezon Master Surgery

K072146

1. SPONSOR

E.M.S. ELECTRO MEDICAL SYSTEMS SA
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

Contact Person: Suzanne Fassio-Hardy
Telephone: 022 994 47 00

DEC 18 2007

Date Prepared: August 2, 2007

2. DEVICE NAME

Proprietary Name:	EMS Piezon Master Surgery
Common/Usual Name:	Bone-cutting instrument and accessories
Classification Name:	Drill, Bone, Powered

3. PREDICATE DEVICES

- Piezosurgery s.r.l. Piezosurgery® (K043408)
- SATELEC Piezotome™ (K060274)

4. INTENDED USE

The EMS Piezon Master Surgery is an ultrasonic bone-cutting instrument for use in surgical dentistry.

5. DEVICE DESCRIPTION

The EMS Piezon Master Surgery is an ultrasonic bone-cutting instrument designed for use in surgical dentistry. The device generates piezo-electric vibrations (ultrasonic energy) for cutting and non-cutting instruments used in surgical dentistry, including oral surgery, implantology, periodontal surgery, and maxillary surgery.

The EMS Piezon Master Surgery device consists of a main chassis containing an irrigation delivery system, an internal electric power supply, a control panel with light-emitting diode (LED) displays, and ultrasonic generator. A one-step footswitch is connected to the main chassis by a footswitch cord and a handpiece containing cutting and non-cutting instruments is connected directly to the main chassis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The EMS Piezon Master Surgery and the predicate devices Piezosurgery s.r.l. Piezosurgery® and SATELEC Piezotome™ generate piezo-electric vibrations (ultrasonic energy) for cutting and non-cutting instruments and are indicated for use in surgical dentistry. Differences between the proposed EMS Piezon Master Surgery and the predicate ultrasonic bone-cutting instruments are limited to design differences in the control panel, irrigation delivery system, and accessories available with each device. Performance testing has been conducted that confirms that the Piezon Master Surgery is able to perform ultrasonic bone-cutting for use in surgical dentistry.

The similarities in intended use, technical specifications, and functional performance between the EMS Piezon Master Surgery, Piezosurgery® and Piezotome™ leads to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

E.M.S. Electro Medical Systems S.A.
C/O Ms. Susan M. Bonapace
Regulatory Associate
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K072146
Trade/Device Name: EMS Piezon Master Surgery
Regulation Number: 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: December 13, 2007
Received: December 14, 2007

Dear Ms. Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

EMS Piezon Master Surgery

Indications for Use:

The EMS Piezon Master Surgery is an ultrasonic bone-cutting instrument for use in surgical dentistry.

Prescription Use __X__ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division [illegible])
Division of [illegible] General Hospital
Infection [illegible]

510(k) Number K072146

SECTION 6
SECTION 7
SECTION 8
SECTION 9
SECTION 5